Prime Herbs
Healthy, Natural, Herbal

K081720

May 1, 2008

PRE-MARKET NOTIFICATION 510 (K) SUMMARY

(As Required by 21 CFR 807.92)

JUN 16 2009

(a)(1)

Submitter:	Prime Herbs Corporation 1872 Hartog Drive San Jose, CA 95131
Contact Person:	Genevieve Hsia
Date Summary Prepared:	May 1, 2008

(a)(2)

Device Trade Name:	Precision TDP Lamp; Precision Heat Lamp; Precision Infrared Lamp; Marvel Lamp; Wonder Lamp
Common or Usual Name:	Infrared Heating Lamp
Device Classification Name:	lamp, infrared, therapeutic heating
Regulation Number:	21 CFR 890.5500
Regulation Name:	Infrared Lamp
Product Code:	ILY
Classification:	Class II
510(k) Number:	K

(a)(3) Substantially Equivalent

This device is substantially equivalent in design and performance to other brands of infrared heating lamps which have been found to be substantially equivalent through the 510(k) premarket notification process. These include the following:

K960036	FIRARD II TDP Lamp	Helio Medical Supplies, Inc
K890556	TDP Infrared Heat Lamp	Toxicology Professionals
K991503	Sacred Crane TDP Lamp CQ27	United Pacific Co.,
K003528	TDP CQ-27 Heat Lamp	Lhasa Medical, Inc

(a)(4) Description

Description of Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp are used to provide topical heating to the body. The Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp are specially engineered using a rare earth

ceramic plate. Emission spectrum ranges from 2 to 50 microns. The emission heating plate should be replaced after 1,200 to 1,500 hours of usage. 110 volt power, 250 watts. It includes timer, safety fuses w/o remote control.

(a)(5) Indications for Use

The Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp may be used for the temporary relief of minor muscle, joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition the Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp may also help muscle spasms, minor sprains and strains, and minor muscular back pan.

(a) (6) Technological Characteristics

The Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp meet the general specifications, criteria, and effectiveness for heat lamps. The Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp also have the same technological characteristics as the predicate devices identified in paragraph (a)(3). The Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp are identical in function, and operation; and uses the same heating plate method and design as these predicate devices.

(b)(1)(2)(3)

Substantial equivalence is not based on an assessment of performance data.

(c) This summary includes these 2 pages in total.

Genevieve Hsia, President

5/1/2008
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2009

Prime Herbs Corporation
Ms. Genevieve Hsia
President
1872 Hartog Drive
San Jose, California 95131

Re: K081720
Trade/Device Name: The Precision TDP Lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: May 8, 2009
Received: May 14, 2009

Dear Ms. Hsia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081720

Device Name: The Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp

Indications for Use:

The Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K081720

(Posted November 13, 2003)